

PATENT SPECIFICATION

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(54) METHOD AND SENSOR DEVICE FOR DETECTING THE LOCATION AND/OR CHARACTER OF A LESION IN BODY TISSUE

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 Laborc-utca, Budapest III., Hungary, a
 body corporate organized under the laws of
 Hungary, do hereby declare the invention
 for which we pray that a patent may be
 granted to us, and the method by which it is
 to be performed to be particularly described
 in and by the following statement:—

The invention relates to a method for
 detecting the location and/or character of a
 lesion in the body tissue in the course of
 which electrodes are put onto or into the
 said tissue, and an electric measuring device
 is connected to the said electrodes in order
 to measure the electric parameters or
 features of the said tissue. The invention
 further relates to a sensor device for the
 performance of the said method, com-
 prising an electric measuring device and a
 pair of measuring electrodes.

Under the title "The modification of the
 electrolyte equilibrium in the malignus
 proliferation of the skin", a survey was
 published in September, 1969 in the medical
 journal Magyar Onkológia on the recent
 research accomplishments and the literature
 sources concerning the establishing of
 lesions in the tissue of the body.

The publications disclose the so-called
 resistance measuring or impedance
 measuring method for the detection of
 lesions in the tissue of the body or
 malignus. One of the most up-to-date
 versions of this method consists in a square-
 wave pulse being supplied to the surface of
 the deformed tissue, the pulse penetrating
 through the said tissue to a sensor electrode
 and appearing on the screen of an oscillo-
 scope coupled to the said electrode, this
 signal then being evaluated. The displayed
 waveform is characteristic of the impedance
 of the tissue of the body. The method as set
 forth above is suitable for the diagnostic
 establishment of lesions in the surface of

the tissue. It is disadvantageous that its
 application is restricted to the detection of
 surface lesions; even if the electrodes
 penetrate the body or its cavities, no
 reliable, valuable detection of lesions can be
 obtained since it is the laminar cuticle the
 decay of which causes a change in the
 capacitive component of the impedance.

The examination of the tissue of the
 body and especially the methods applied in
 the diagnosis of tumours are rather
 sophisticated and time-consuming. The
 minimum duration of a conventional histo-
 logical examination amounts to 24 hours.
 Although the examination of quickfrozen
 excisions can be performed within only 10
 minutes or so, such a method can only be
 performed successfully by experts with
 specialist skills in this field since the quick-
 freezing process destroys the cells.

A well-known diagnostic method is the
 one utilizing radioactive isotopes but for
 this purpose expensive equipment is needed
 and furthermore there is the disadvantage
 of radiation damage.

Thermometric examinations are not suit-
 able because of their lack of reliability.

Ultrasonic examinations can detect the
 location of lesions in tissues but no infor-
 mation can be obtained concerning the
 character of the said lesion.

The uncertainty in establishing a tumour
 is 17,5% for X-ray examinations, 39% for
 gastroscopy, and 21% for cytology.

It has already been mentioned that the
 measurement of the resistance or the
 conductivity according to prior art is only
 suitable for the detection of lesions
 appearing at the surface of the skin or in
 tissue covered immediately by cuticles; the
 measured value is affected by many factors
 such as the structure of the tissue, and the
 state of the surface of the tumour, i.e.
 whether the surface is intact or not.

The invention aims to make it possible to

establish the location and/or the character of a lesion in body tissue by a diagnostic method, and to provide a sensor device suitable even in cases when the tumour is
5 embedded in the tissue of the body, the device being quick and reliable to operate without the need of a sample excision.

The invention is based on the realisation that such a diagnostic method can be found
10 if utilising a special feature of the tissue, viz. the fact that the electrolytic strength of the malignant tissues is of a higher value than that of sound tissue. It has been realised that two electrodes of different
15 substances and electrode potentials if put into the said tissue—may be considered to form a primary cell supplying a potential that is in itself not characteristic of the electrolytic concentration of the tissue on
20 open circuit of the cell. However the ability of the cell to provide sustained current is dependent on the electrolytic concentration of the tissue.

According to one aspect of the invention
25 there is provided a method for detecting the location and/or character of a lesion in living tissue, wherein two electrodes of differing electrode potentials are placed onto or into the tissue the electrodes being
30 connected to the terminals of an electric current measuring device which has a small internal resistance such that the current flowing through the device and between the electrodes is measured by the device and is
35 representative of the electrolytic concentration of the tissue between the electrodes.

It is expedient to compare the measured value of the current flowing between the
40 electrodes with the value measured in the same manner on a piece of sound tissue.

The sensor device suitable for the performance of the said method comprises two electrodes having differing electrode potentials and a current measuring device for
45 connection across the electrodes when the latter are placed into or on the tissue, the electrodes being provided by either:—

(i) two electrically conducting, concentric
50 members separated by electrically insulating material with one end of the inner member being exposed to form one electrode surface and the corresponding end of the outer member forming the other electrode
55 surface, the extremity of said one end of the inner member being coplanar with or projecting beyond the extremity of said one end of the outer member or,

(ii) two pivotally interconnected jaws of a
60 sample excision spoon, the parts being pivotally mounted on an insulating stem of the spoon.

It is an advantage of the method and the sensor device according to the invention
65 that the location and the character of

tumours embedded in body tissue can immediately and reliably be established without the need of making a sample excision. This way it is possible to detect lesions also by endoscopy, puncture or
70 biopsy.

The invention will now be set forth more particularly with reference to the accompanying drawings showing preferred
75 embodiments of the sensor device.

Figure 1 shows a sensor device adapted from a medical syringe.

Figure 2 shows a sensor device adapted from a sample excision spoon with open jaws whereas Figure 3 shows the sensor
80 device of Figure 2 but with closed jaws.

It can be seen in Figure 1 that the diagnostic sensor device according to the invention utilizes a tubular medical syringe 1
85 itself. One of the electrodes of the sensor device is formed by the metal syringe 1 itself. Inside the tube of the syringe 1 is an inner electrode 3 with insulating material 2 disposed between the syringe 1 and the
90 electrode 3. The inner electrode 3 is of a different substance from that of the syringe 1, i.e. their electrode potentials as compared with that of hydrogen are different. If the syringe 1 is made of stainless steel, the inner
95 electrode 3 can e.g. be made of magnesium or carbon. The insulating material 2 is "Teflon"®. The active end surface of the inner electrode 3 can be arranged in the same plane as the end surface of the
100 insulating material 2 and the end of the syringe 1, or it can project from the syringe. The syringe 1 and the electrode 3 are coupled to the input terminals of a current
meter 7.

Figures 2 and 3 show another embodiment of the sensor device according to the invention. The sensor device is adapted
105 from a sample excision spoon as known in the prior art. Two jaws 4 and 5 of the said spoon (forming electrodes) are pivotally mounted on an insulating stem 6, and the jaws 4 and 5 are made of different metals
110 the electrode potentials of which (as compared with that of hydrogen) are different. The jaws 4 and 5 are provided with terminals led through the insulating stem 6 and coupled to the input terminals of the
115 current meter 7.

The sensor devices as set forth above can advantageously be applied for performing
120 the diagnostic method according to the invention. The essence of the method according to the invention consists in that the two electrodes of different materials are put onto or into the body tissue, the electrodes
125 are connected across a measuring device having a small internal resistance and the substantial current flowing through the terminals of the said electrodes is measured, whereupon the measured value of the
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current flowing between the electrodes may be compared with the value measured in the same way on a piece of sound tissue.

The method is based on the phenomenon that the electrolytic strength of malignant tissues is higher than that of sound tissue. The electrolyte is utilized as the electrolyte of the primary cell constituted by the said electrodes led into the tissue. The ability of the primary cell to produce current is characteristic of the electrolytic strength. Theoretically, the open-circuit voltage of the primary cell is independent of the electrolytic strength. In practice however, even without external load, some dependence of the cell voltage on electrolytic strength can be explained by the fact that the internal resistance of the body itself constitutes a load on the primary cell established within the tissue of the body. This load effect is to a great measure determined by the dimensions and arrangement of the electrodes, by the volume of the tissue surrounding the said electrodes, and the electrolytic strength.

The uncertainty caused by the said internal conductivity of the body is compensated if the electrodes are connected to the measuring device.

The electrodes can be made of any good electrical conductor (e.g. metal) provided that they are of different materials. The e.m.f. of the primary cell is dependent on the distance of the two metals from each other in the electrochemical series; the greater the distance the greater the voltage drop that can be permitted over the current meter 7.

The sensitivity of the current meter 7 coupled between the electrodes is to be chosen in dependence on the substance and the dimensions of the electrodes. If, e.g., the sensor device as shown in Figure 1 comprises an external electrode 1 of stainless steel, and the diameter of the tube amounts to 1 mm whereas the inner electrode consists of magnesium and the active end surface is a circle of 0.8 mm diameter, then a sound mycoderm of the stomach effects a current of about 130–140 μ A whereas a stomach adenocarcinoma causes an increase of this current to about 220–230 μ A. If one increases the active surface of the magnesium electrode, a proportional increase of the galvanic current established in the tissue can be obtained.

The method according to the invention can be applied in the field of skin tumour diagnostics, laryngology, gynaecology, and combinable endoscopic examinations. The method is suitable not only for the detection of permanent lesions in the tissue but even transitional changes in the state of the tissue can be detected and, thus, quick modifications in the process of life can be recog-

nized such as the prospective date of childbirth or a danger menacing the foetus by examining the surface of the caul. The method can be applied in order to detect, the state preceding the cancerosis in the tissue of the body. The method makes it possible to draw conclusions concerning the state of the space inside the cell, e.g. loss of fluid in case of internal haemorrhage, inflammatory oedema by examining the surface mycodermis in the mouth or on the tongue. The time necessary to make a diagnosis—if applying this method—is diminished from hours to seconds and the result is even more exact than in the case of microscopic examinations. If one standardizes the electrodes and the measuring conditions, the malignant process can also be characterized by the absolute value of the current.

The location of the lesion in the tissue of the body can e.g. be established by inserting the electrodes in sequence at different points into the tissue and reading the current values the change of which shows the boundaries of the abnormal tissue.

WHAT WE CLAIM IS:—

1. A method for detecting the location and/or character of a lesion in living tissue, wherein two electrodes of differing electrode potentials are placed onto or into the tissue, the electrodes being connected to the terminals of an electric current measuring device which has a small internal resistance such that the current flowing through the device and between the electrodes is measured by the device and is representative of the electrolytic concentration of the tissue between the electrodes.

2. A method according to claim 1, wherein the measured value of current flowing between the electrodes is compared with a value of current measured in a comparable manner between similar electrodes placed onto or in sound tissue.

3. A sensor device when used in the method of claim 1 or claim 2, comprising two electrodes having differing electrode potentials and a current measuring device for connection across the electrodes when the latter are placed into or on the tissue, the electrodes being provided by either:—

(i) two electrically conducting, concentric members separated by electrically insulating material with one end of the inner member being exposed to form one electrode surface and the corresponding end of the outer member forming the other electrode surface, the extremity of said one end of the inner member being coplanar with or projecting beyond the extremity of said one end of the outer member, or

(ii) two pivotally interconnected jaws of a sample excision spoon, the parts being pivotally mounted on an insulating stem of

the spoon.

4. A method according to claim 1 substantially as herein described with reference to and as shown in Figure 1 or Figures 2 and 3 of the accompanying drawings.

5. A sensor device according to claim 3 substantially as herein described with reference to and as shown in Figure 1 of the accompanying drawings.

- 10 6. A sensor device according to claim 3

substantially as herein described with reference to and as shown in Figures 2 and 3 of the accompanying drawings.

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COMPLETE SPECIFICATION

1 SHEET

This drawing is a reproduction of
the Original on a reduced scale

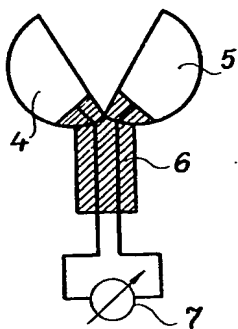


Fig. 2

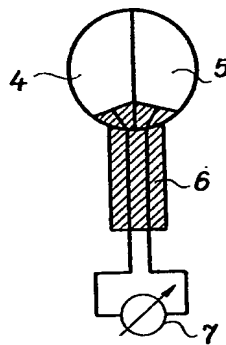


Fig. 3

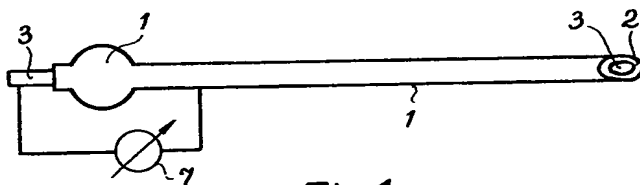


Fig. 1

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